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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,819	11/06/2000	Akira Aomatsu	5774-01-MJA	5038

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,819

Applicant(s)

AOMATSU, AKIRA

Examiner

MY-CHAU T. TRAN

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,35-37,40,41 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28,35-37,40,41 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application and Claims Status

1. Applicant's amendment filed 09/12/2006 and response filed 04/24/2006 are acknowledged and entered.
2. Claims 28, 35-37, 40, and 41 were pending. Applicants have amended claims 28, 35, 37, and 41 and added claim 43. No claims were cancelled. Therefore, claims 28, 35-37, 40, 41, and 43 are currently pending and are under consideration in this Office Action.

Election/Restrictions

3. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected the following species for the elected invention (Claims 28, 35-37, 40, and 41) in the reply filed on 03/08/2005:

- a. A *single specific* species of humectant. Applicant has elected propylene glycol.
However, the election is moot since applicant deleted the term "humectant" and cancelled claims 29 and 31-34 in the amendment filed 11/07/2005.
- b. A *single specific* species of auxiliary agent. Applicant has elected hydroxypropylcellulose.
- c. A *single specific* species of neutral amino acid. Applicant has elected glycine.
However, the election is moot since applicant cancelled claims 38 and 39 in the amendment filed 11/07/2005.

Status of Claim(s) Objection(s) and/or Rejection(s)

4. The rejection of claims 28, 35-37, 40, and 41 under 35 USC 103(a) as being obvious over Jao et al. (US Patent 5,660,861) and Giacin et al. (US Patent 5,302,373) has been withdrawn in view of applicant's amendments of claims 28, 35, 37, and 41 wherein applicant deleted the term "humectant".

New Rejection(s)

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 28, 36, 40, and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Schrier et al. (WO 98/58,641):

For ***claim 28***, Schrier et al. disclose methods of using analogs of gamma aminobutyric acid (GABA) and pharmaceutical compositions of a GABA analog (see e.g. Abstract; pg. 1, lines 6-7; pg. 2, line 16 thru pg. 5, line 11). The pharmaceutical compositions comprise the active compound, i.e. GABA analog; in dosage unit forms with a pharmaceutical carrier (see e.g. pg. 4, line 17 thru pg. 5, line 11). The pharmaceutical carrier includes pharmaceutical diluents such as propylene glycol and sorbitol (see e.g. pg. 4, lines 22-28). The GABA analog include compound such as gabapentin (see e.g. pg. 2, line 16 thru pg. 3, line 1).

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For *claim 36*, Schrier et al. disclose that the composition also include other component such as coloring agents, flavoring agents, and/or preservatives (refers to instant claimed an auxiliary agent)(see e.g. pg. 4, line 31 thru pg. 5, line 2).

For *claim 40*, Schrier et al. disclose that the dosage unit forms include tablets, capsules and pills (see e.g. pg. 4, lines 19-22).

For *claim 41*, Schrier et al. disclose that the compositions are produced by formulating the active compound in dosage unit form with a pharmaceutical carrier that include diluent (see e.g. pg. 4, lines 17-31).

Therefore, the composition of Schrier et al. does anticipate the instant claimed invention.

7. Claims 28 and 43 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schrier et al. (WO 98/58,641).

For *claim 28*, Schrier et al. disclose methods of using analogs of gamma aminobutyric acid (GABA) and pharmaceutical compositions of a GABA analog (see e.g. Abstract; pg. 1, lines 6-7; pg. 2, line 16 thru pg. 5, line 11). The pharmaceutical compositions comprise the active compound, i.e. GABA analog, in dosage unit forms with a pharmaceutical carrier (see e.g. pg. 4, line 17 thru pg. 5, line 11). The pharmaceutical carrier includes pharmaceutical diluents such as propylene glycol and sorbitol (see e.g. pg. 4, lines 22-28). The GABA analog include compound such as gabapentin (see e.g. pg. 2, line 16 thru pg. 3, line 1).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of:

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For **claim 43**, the limitations that *'after storage of the composition in a sealed container at 60°C for 2 weeks the content of the corresponding lactam that is formed in the composition is less than 0.20% by weight relative to the initial amount of the 4-amino-3-substituted-benzoic acid derivative in the composition'* is interpreted as the process limitation for the instantly composition. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Schrier et al. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). As a result, the composition of Schrier et al. would still anticipate the presently claimed composition since it meets all the structural limitation of the claimed composition of claim 28, i.e. a composition comprising gabapentin and propylene glycol.

Therefore, the composition of Schrier et al. does anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 28, 35-37, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier et al. (WO 98/58,641).

For **claim 28**, Schrier et al. disclose methods of using analogs of gamma aminobutyric acid (GABA) and pharmaceutical compositions of a GABA analog (see e.g. Abstract; pg. 1, lines 6-7; pg. 2, line 16 thru pg. 5, line 11). The pharmaceutical compositions comprise the active compound, i.e. GABA analog, in dosage unit forms with a pharmaceutical carrier (see e.g. pg. 4, line 17 thru pg. 5, line 11). The pharmaceutical carrier includes pharmaceutical diluents such as propylene glycol and sorbitol (see e.g. pg. 4, lines 22-28). The GABA analog include compound such as gabapentin (see e.g. pg. 2, line 16 thru pg. 3, line 1).

For **claim 36**, Schrier et al. disclose that the composition also include other component such as coloring agents, flavoring agents, and/or preservatives (refers to instant claimed an auxiliary agent)(see e.g. pg. 4, line 31 thru pg. 5, line 2).

For **claim 40**, Schrier et al. disclose that the dosage unit forms include tablets, capsules and pills (see e.g. pg. 4, lines 19-22).

For **claim 41**, Schrier et al. disclose that the compositions are produced by formulating the active compound in dosage unit form with a pharmaceutical carrier that include diluent (see e.g. pg. 4, lines 17-31).

The teachings of Schrier et al. differs from the presently claimed invention as follows:

For **claims 35 and 37**, Schrier et al. fail to disclose that propylene glycol total amount is 0.01-25% by weight relative to the active ingredient and/or auxiliary agent.

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However, Schrier et al. disclose that in the solid form the active ingredient is at least 10% and up to about 95% (see e.g. pg. 5, lines 6-11), which would suggest that the amount of the pharmaceutical diluents would range from about 5% to about 90%.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose that propylene glycol total amount is 0.01-25% by weight relative to the active ingredient and/or auxiliary agent in the composition of Schrier et al. One of ordinary skill in the art would have been motivated to disclose that propylene glycol total amount is 0.01-25% by weight relative to the active ingredient and/or auxiliary agent in the composition of Schrier et al. because the concentration of propylene glycol would be a choice of experimental design and is considered within the purview of the cited prior art. Additionally, it has been held that "*where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.*" See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA1955). Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in having the amount propylene glycol in the range of 0.01-25% by weight relative to the active ingredient and/or auxiliary agent in the composition of Schrier et al. since this range imply that the active ingredient is in the range of 75-99.99%, which fall within the range of active ingredient of the solid form of Schrier et al.

Therefore, the teachings of Schrier et al. do render the composition of the instant claims *prima facie* obvious.

Conclusion

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCT
October 26, 2006

PETER PARAS, JR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

A handwritten signature in black ink, appearing to read "Peter Paras, Jr.", is written over the printed name and title.